Docket No.: 18264 (64095201)
Application No.: 10/736,662
Reply to Notice of Non-Compliant Amendment mailed December 8, 2006

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Please cancel claims 1, 2, 4-7.

1. (cancelled) A method of detecting the premature rupture of amniotic membrane comprising testing vaginal fluid for pH and determining a result as an irreversible change in a testing medium.
2. (cancelled) The method of claim 1 wherein said irreversible change is a color change.
3. (withdrawn) The method of claim 1 wherein said irreversible change is production of a hydrogel.
4. (cancelled) The method of claim 2 wherein said testing for pH is performed using liposomes that undergo an irreversible hyperchromic spectral shift in response to an elevated environmental pH.
5. (cancelled) The method of claim 4 wherein said elevated pH is a pH of at least 6.
6. (cancelled) The method of claim 4 wherein said elevated pH is a pH of at least 7.
7. (cancelled) The method of claim 4 wherein said liposomes are selected from the group consisting of 10,12-pentacosadiynoic acid derivatized with glutamic acid, and 3-(dimethylamino)propylamine.
8. (withdrawn) The method of claim 2 wherein said testing is performed using the steps of encapsulating a pH insensitive dye with a pH sensitive encapsulating material.
9. (withdrawn) A method of detecting the premature rupture of amniotic membrane, comprising: a first step selected from the group consisting of testing vaginal fluid pH and determining a result as an irreversible change, detecting amniotic fluid analyte in vaginal fluid, detecting hydrogen peroxide in vaginal fluid, and detecting cholesterol in vaginal fluid; and,

   a second step, different from said first step, and selected from the group consisting of testing vaginal fluid pH and determining a result as an irreversible change, detecting amniotic fluid analyte in vaginal fluid, detecting hydrogen peroxide in vaginal fluid, and detecting cholesterol in vaginal fluid, wherein said first and second steps indicate premature rupture of amniotic membrane.
10. (withdrawn) The method of claim 9 further comprising a third step, different from the first and second steps, and selected from the group consisting of testing vaginal fluid pH and determining a result as an

irreversible change, detecting amniotic fluid analyte in vaginal fluid, detecting hydrogen peroxide in vaginal fluid, and detecting cholesterol in vaginal fluid.

11. (withdrawn) The method of claim 9 wherein one of said steps is detecting amniotic fluid analyte in vaginal fluid, which results in a color change.

12. (withdrawn) The method of claim 11 wherein said analyte is chosen from the group consisting of alkaline phosphatase, diamine oxidase, monoaminc oxidase, pepsinogen, alpha-galactosidase, alpha-fucosidase, amylase, alpha-mannosidase, lysozyme, phosphatidic acid, phosphohydrolase, fetal fibronectin, alpha fetoprotein, collagen breakdown pads, estradiol, active ceruloplasmin, aderenomedullin, insulin-like growth factor-binding protein, inhibin B, human chorionic gonadotropin, human placental lactogen, granulocyte elastase, prolactin, fructose-based fatty acids, phospholipids, lecithin, uric acid, urea, creatinine and rennin.

13. (withdrawn) The method of claim 9 wherein one of said steps is detecting hydrogen peroxide in vaginal fluid and said detecting of hydrogen peroxide results in a color change.

14. (withdrawn) The method of claim 13 wherein said color change is produced by a reaction between said hydrogen peroxide and a peroxidase substrate.

15. (withdrawn) The method of claim 9 wherein one of said steps is detecting cholesterol in vaginal fluid and said detecting of cholesterol results in a color change.

16. (withdrawn) The method of claim 15 wherein said color change is produced by a series of enzyme-based reactions including 4-aminoantipyrine.

17. (withdrawn) The method of claim 9 comprising detecting amniotic fluid analyte in vaginal fluid by depositing a ligand receptor for an analyte in a first area of a feminine hygiene pad,

depositing a receptor specific to an alternate site on the analyte in a second area of said pad, and;

testing for pH by depositing cross-linked liposomes in a third area of said pad, wherein fluid entering said pad is channeled to the ligand receptor deposit, then to the alternate site receptor and then to the third area of said pad, resulting in a visual indication of PROM.

18. (withdrawn) The method of claim 9 comprising encapsulating an analyte sensitive dye within a capsule made from a pH sensitive encapsulating material with a pKa greater than 6.5 and less than 7, wherein said capsule releases said analyte sensitive dye and said dye changes color in amniotic fluid.
19. (withdrawn) The method of claim 9 comprising encapsulating a pH sensitive dye within a capsule made from an analyte sensitive encapsulating material, wherein said capsule releases said pH sensitive dye and said dye changes color in amniotic fluid.
20. (withdrawn) The method of claim 9 comprising coupling alpha-galactoside to phenolic groups of a phenolphthalein, wherein said alpha-galactosidase is cleaved and the phenolphthalein changes color in amniotic fluid.
21. (withdrawn) The method of claim 20 further comprising the step of encapsulating alpha-galactosidase coupled phenolphthalein within an analyte sensitive capsule.
22. (withdrawn) A feminine hygiene article comprising indicators selected from the group consisting of pH sensitive liposomes and pH sensitive capsules having a pH insensitive dye within.
23. (withdrawn) A feminine hygiene article comprising a ligand receptor for an analyte deposited in a first area of the article and a receptor specific to an alternate site on the analyte in a second area of said article, wherein fluid entering said article is channeled to the ligand receptor deposit and then to the alternate site receptor, resulting in a visual indication of said analyte.
24. (withdrawn) The article of claim 23 wherein said analyte is selected from the group consisting of alkaline phosphatase, diamine oxidase, monoamine oxidase, pepsinogen, alpha-galactosidase, alpha-fucosidase, amylase, alpha-mannosidase, carbohydrate-based enzymes, lysozyme, phosphatidic acid, phosphohydrolase, fetal fibronectin, alpha fetoprotein, collagen breakdown articles, estradiol, active ceruloplasmin, aderenomedullin, insulin-like growth factor-binding protein, inhibin B, human chorionic gonadotropin, human placental lactogen, granulocyte elastase, prolactin, fructose-based fatty acids, lipids, uric acid, urea, creatinine and renin.

25. (withdrawn) The article of claim 23 comprising a hydrazine and a galactoside acetal of a ketone-containing polymer, and a buffer, wherein said acetal is enzymatically hydrolyzed by amniotic fluid, and the ketone is liberated to react with the hydrazine to form hydrazone.
26. (withdrawn) A lateral flow test for the detection of PROM comprising liposomes that undergo an irreversible hyperchromic spectral shift in response to an elevated environmental pH in first location on said lateral flow test and a peroxidase substrate in a second location on said test, wherein a sample of fluid passes through said first and second locations by capillary action.
27. (withdrawn) A cell button device having a pH side and a peroxide side, wherein a sample of fluid introduced on the pH side will indicate a pH and then pass to the peroxide side and indicate peroxide.

Please enter the following new claims 28-41.

28. (New) A method for detecting premature rupture of amniotic membrane, the method comprising: testing a sample of vaginal secretion for pH using a first visual indicator that results in an irreversible change and detecting using the first or a second visual indicator for a relative presence in said vaginal secretion of at least one of the following species: a) hydrogen-peroxide (H_2O_2) level, b) analytes specific to amniotic fluid, c) cholesterol, d) or a combination of a), b) or c) species.
29. (New) The method according to claim 28, wherein said vaginal secretion has a pH-level greater than 5 during pregnancy.
30. (New) The method according to claim 28, wherein said H_2O_2 level is detected with a hydrogen-peroxide-mediated enzymatic and non-enzymatic conversion of chromophores.
31. (New) The method according to claim 30, wherein said H_2O_2 reacts with a peroxidase-treated substrate.
32. (New) The method according to claim 28, wherein said detection indicates a relative decrease in said H_2O_2 level from normal levels.
33. (New) The method according to claim 28, wherein said method comprises testing said sample of vaginal secretion for an elevated pH-level greater than a normal vaginal pH range during pregnancy and detecting a relative decrease in said H_2O_2 level from normal levels.
34. (New) The method according to claim 33, wherein said pH-level is at least 6.
35. (New) The method according to claim 28, wherein said analytes include: alkaline phosphatase, diamine oxidase, monoamine oxidase, pepsinogen, alpha-galactosidase, alpha-fucosidase, amylase, alpha-mannosidase, lysozyme, phosphatidic acid, phosphohydrolase, fetal fibronectin, alpha

fetoprotein, collagen-breakdown products, estradiol, active ceruloplasmin, aderenomedullin, insulin-like growth factor-binding protein, inhibin B, human chorionic gonadotroprin, human placental lactogen, granulocyte elastase, prolactin, fructose-based fatty acids, phospholipids, lecithin, uric acid, urea, creatinine and rennin.

36. (New) The method according to claim 28, wherein said cholesterol is present in a concentration range of about 20-100mg/L.

37. (New) The method according to claim 28, wherein either said cholesterol or said analytes in amniotic fluid results in a visible color change on a detecting apparatus.

38. (New) The method according to claim 37, wherein said color change for cholesterol detection involves a series of enzyme-based reactions including 4-aminoantipyrine.

39. (New) The method according to claim 28, further comprising: detecting amniotic fluid analyte in vaginal secretion by depositing a ligand receptor for an analyte in a first area of a feminine hygiene product, depositing a receptor specific to an alternate site on the analyte in a second area of said pad, and testing for pH by depositing cross-linked liposomes in a third area of said hygiene product, wherein fluid entering said product is channeled to the ligand receptor deposit, then to the alternate site receptor and then to the third area of said product, resulting in a visual indication of premature rupture of membrane.

40. (New) The method according to claim 28, further comprising: encapsulating an analyte sensitive dye within a capsule made from a pH sensitive encapsulating material with a pKa greater than 6.5 and less than 7, wherein said capsule releases said analyte sensitive dye and said dye changes color in amniotic fluid.

41. (New) The method according to claim 28, further comprising: encapsulating a pH sensitive dye within a capsule made from an analyte sensitive encapsulating material, wherein said capsule releases said pH sensitive dye and said dye changes color in amniotic fluid.